



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#10

In re the application of: Bujard, Hermann *et al.*

Serial No.: 09/874389

Filed: June 4, 2001

For: *TRANSGENIC ORGANISMS HAVING
TETRACYCLINE-REGULATED
TRANSCRIPTIONAL REGULATORY SYSTEMS*

Attorney Docket No.: BBI-009C3CN2

Group Art Unit: 1638

Examiner: Not Yet Assigned

Commissioner for Patents
Washington, D.C. 20231

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March 31, 2003

Date of Signature and of Mail Deposit

By:

DeAnn F. Smith, Esq.
Registration No. 36,683
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

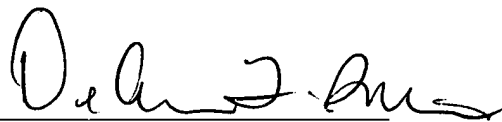
For the Examiner's convenience in reviewing this continuation application, Applicant submits a consolidated PTO Form 1449, listing all references cited during the prosecution of the parent application. The present application is a Continuation of U.S. Serial No. 09/161902, filed September 28, 1998 (Atty. Docket No. BBI-009C3CN), which is a Continuation of U.S. Serial No. 08/487472, filed June 7, 1995, which is a Continuation-In-Part of U.S. Serial No. 08/383754, filed February 3, 1995, issued as U.S. Patent No. 5,789,156 which is a Continuation-In-Part of U.S. Serial No. 08/275876, filed July 15, 1994, issued as U.S. Patent No. 5,654,168, which is a Continuation-In-Part of U.S. Serial No. 08/270637, filed

July 1, 1994, now abandoned. U.S. Serial No. 08/487,472 is also a Continuation-In-Part of U.S. Serial No. 08/260452, filed June 14, 1994, issued as U.S. Patent No. 5,650,298, which is a Continuation-In-Part of U.S. Serial No. 08/076327, filed June 14, 1993, now abandoned. U.S. Serial No. 08/487,472 is also a continuation-in-part of U.S. Serial No. 08/076,726, filed June 14, 1993, used as U.S. Patent No. 5,464,758. All references listed on the enclosed PTO Form 1449 have been previously cited by or submitted to the Office in the prior applications, and, in accordance with 37 CFR §1.98(d), copies of the references are not enclosed but will be provided upon request.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,
LAHIVE & COCKFIELD, LLP



DeAnn F. Smith Esq.
Registration No. 36,683
Attorney for Applicants

28 State Street
Boston, MA 02109
(617) 227-7400

Date: March 31, 2003

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LIST OF PUBLICATIONS CITED BY APPLICANT
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APPLICANT

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	4,833,080	05/89	Brent et al.	435	69	
	A2	5,221,778	06/93	Byrne et al.	800	21	
	A3	5,464,758	11/95	Gossen et al.	435	69	
	A4	5,545,808	08/96	Hew et al.	800	3	
	A5	5,595,895	01/97	Miki et al.	435	6	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	A6	0 332 416	09/89	EP				
	A7	0 455 687 B1	11/91	EP				
	A8	0 455 424 A2	11/91	EP				
	A9	0 494 724 A2	07/92	EP				
	A10	WO 91/13979	09/91	WO				
	A11	WO 91/19796	12/91	WO				
	A12	WO 91/19784	12/91	WO				
	A13	WO 92/11874	07/92	WO				
	A14	WO 92/20808	11/92	WO				
	A15	WO 93/04169	03/93	WO				
	A16	WO 93/23431	11/93	WO				
	A17	WO 94/04672	03/94	WO				
	A18	WO 94/18317	08/94	WO				
	A19	WO 94/29442	12/94	WO				
	A20	WO 96/01313	01/96	WO				

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	A21	Ackland-Berglund, C.E., and Leib, D.A. (1995) "Efficacy of Tetracycline-Controlled Gene Expression Is Influenced by Cell Type" <i>BioTechniques</i> 18(2):196-200.
	A22	Ackland-Berglund, C.E. and Leib, D.A. (1995) "Biofeedback" <i>BioTechniques</i> 19:216-217.
	A23	Agarwal, M.L. et al. (1995) "p53 Controls Both the G ₂ /M and the G ₁ Cell Cycle Checkpoints and Mediates Reversible Growth Arrest in Human fibroblasts," <i>Proc. Natl. Acad. Sci. USA</i> , 92:pp. 8493-8497.
	A24	Altschmied, L. et al., (1988) "A threonine to alanine exchange at position 40 of Tet repressor alters the recognition of the sixth base pair of tet operator from GC to AT", <i>The EMBO Journal</i> , vol. 7, No. 12, pp. 4011-4017.
	A25	Baim, S.B., et al., (1991) "A chimeric mammalian transactivator based on the lac repressor that is regulated by temperature and isopropyl .beta.-D-thiogalactopyranoside", <i>Proceedings of the National Academy of Science</i> , vol. 88, pp. 5072-5076.

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B1	Baniahmad, A. et al. (1992) "A Transferable Silencing Domain Is Present In the Thyroid Hormone Receptor, In the v-erbA Oncogene Product and In the Retinoic Acid Receptor" <i>The EMBO Journal</i> 11(3):1015-1023.
B2	Baumeister, R. et al. (1992) "Contacts Between Tet Repressor And tet Operator Revealed By New Recognition Specificities Of Single Amino Acid Replacement Mutants", <i>Journal Of Molecular Biology</i> , vol. 226, pp. 1257-1270.
B3	Baumeister, R. et al. (1992) "Functional Roles Of Amino Acid Residues Involved In Forming The α -helix-turn- α -helix operator DNA Binding Motif Of Tet repressor From Tn10", <i>Proteins: Structure, Function, and Genetics</i> , vol. 14(2), pp. 168-177.
B4	Baumeister, R. et al. (1992) "Tet Repressor Tet Operator Interactions Derived From Mutants With New Recognition Specificities", <i>Structural Tools For The Analysis Of Proten-Nucleic Acid Complexes Advances In Life Sciences</i> , pp. 175-183.
B5	Bergman, M. et al. "Overexpressed Csk Tyrosine Kinase Is Localized in Focal Adhesions, Causes Reorganization of $\alpha_v \beta_5$ Integrin, and Interferes with HeLa Cell Spreading", <i>Molecular and Cellular Biology</i> , 15, No. 2, pp. 711-722 (1995).
B6	Boshart, M., et al., (1985) "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus", <i>Cell</i> , vol. 41, No. 2, pp. 521-530.
B7	Bradley, A. et al., (1992) "Modifying The Mouse: Design And Desire", <i>Biotechnology</i> , vol. 10, pp. 534-539.
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B9	Brent R. and M. Ptashne (1985) "A Eukaryotic Transcriptional Activator Bearing the DNA Specificity of a Prokaryotic Repressor" <i>Cell</i> 43:729-736.
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B12	Buckbinder L. et al. (1994) "Gene Regulation by Temperature-Sensitive p53 Mutants: Identification of p53 response genes" <i>Proc. Natl. Acad. Sci. USA</i> 91:10640-10644.
B13	Capecchi, M.R., (1989) "Altering the Genome by Homologous Recombination", <i>Science</i> , vol. 244, pp. 1288-1292.
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B15	Chen, Y.Q. et al. "Tumor Suppression by p21 ^{WAF1} ", <i>Cancer Research</i> , 55, pp. 4536-4539, (1995).
B16	Coghlan, A. "Gene dream fades away" <i>New Scientist</i> 148, pp. 14-15, (1995).
B17	Courey, A.J., and Tjian, R., (1988) "Analysis of Sp1 In Vivo Reveals Multiple Transcriptional Domains, Including a Novel Glutamine-Rich Activation Motif", <i>Cell</i> , vol. 55, pp. 887-898.
B18	Cowell, "Repression versus activation in the control of gene transcription," <i>Trends in Biochemical Sciences</i> , 19:1, 38-42 (1994).

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OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

C1	Crystal, R.G. "Transfer of Genes to Humans: Early Lessons and Obstacles to Success", <i>Science</i> 270, pp. 404-410 (1995).
C2	Daddona et al., "Human Adenosine Deaminase." <i>J. Biol. Chem.</i> 259: 12101-12106 (1984).
C3	Damke, H. et al. "Induction of Mutant Dynamin Specifically Blocks Endocytic Coated Vesicle Formation." <i>The Journal of Cell Biology</i> 127 (4): 915-934.
C4	Damke, H. et al. "Tightly Regulated and Inducible Expression of Dominant Interfering Dynamin Mutant in Stably Transformed HeLa Cells." <i>Methods in Enzymology</i> 257: 209-220 (1995).
C5	Degenkolb, J., et al., (1991) "Structural Requirements of Tetracycline-Tet Repressor Interaction: Determination of Equilibrium Binding Constants for Tetracycline Analogs with the Tet Repressor", <i>Antimicrobial Agents and Chemotherapy</i> , vol. 35, No. 8, pp. 1591-1595.
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C8	Dhawan, J. et al. "Tetracycline-Regulated Gene Expression Following Direct Gene Transfer into Mouse Skeletal Muscle", <i>Somatic Cell and Molecular Genetics</i> , 21, No. 4, pp. 233-240, (1995).
C9	Ebert, K.M. et al. (1988) "A Moloney MLV-Rat Somatotropin Fusion Gene Produces Biologically Active Somatotropin in a Transgenic Pig." <i>Molecular Endocrinology</i> 2(3): 277-283.
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D1	Gatz, C., and Quail, P.H., (1988) "Tn10-encoded tet repressor can regulate an operator-containing plant promoter", <i>Proceedings of the National Academy of Science</i> , vol. 85, pp. 1394-1397.
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D3	Gjetting, T. et al. "Regulated Expression of the Retinoblastoma Susceptibility Gene in Mammary Carcinoma Cells Restores Cyclin D1 Expression and G ₁ -Phase Control", <i>Biol. Chem. Hoppe-Seyler</i> , 376, pp. 441-446 (1995).
D4	Gossen et al. (1994) "Inducible Gene Expression Systems For Higher Eukaryotic Cells" <i>Current Opinion in Biotechnology</i> 5:516-520.
D5	Gossen et al., "Exploiting prokaryotic elements for the control of gene activity in higher eukaryotes," Keystone Symposium on Gene Therapy and Molecular Medicine, Steamboat Springs, Colorado, <i>Journal of Cellular Biochemistry</i> , Supplement 0 (21A), Abstract No. C6-220, 355 (1995).
D6	Gossen et al., "Transcriptional activation by tetracyclines in mammalian cells," <i>Science</i> , 268:5218, 1766-1769 (1995).
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D10	Gunzburg, W.H. and Salmons, B. "Virus vector design in gene therapy", <i>Molecular Medicine Today</i> 1, pp. 410-417, (1995).
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E1	Howe, J.R. et al. "The Responsiveness of a Tetracycline-Sensitive Expression System Differs in Different Cell Lines", <i>The Journal of Biological Chemistry</i> , 270, No. 23, pp. 14168-14174, (1995).
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E3	Kappel, C.A., et al., (1992) "Regulating Gene Expression In Transgenic Animals", <i>Current Opinion In Biotechnology</i> , vol. 3, pp. 548-553.
E4	Krimpenfort, P. et al. "Generation of Transgenic Dairy Cattle Using 'in vitro' Embryo Production." <i>Bio/Technology</i> 9, pp. 844-847 (1991).
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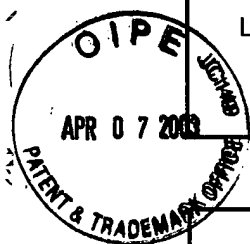
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F9	Seipel, K., et al., (1992) "Different activation domains stimulate transcription from remote ('enhancer') and proximal ('promoter') positions", <i>The EMBO Journal</i> , vol. 11, No. 13, pp. 4961-4968.
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